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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HUH, BENJAMIN	
ART UNIT	**PAPER NUMBER**
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,591	DUCHON ET AL.	
	Examiner	Art Unit	
	Benjamin Huh	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/20/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/18/05, 11/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Additional IDS Statements: 3/24/05, 10/11/05, 1/20/06, 7/6/04.

DETAILED ACTION

Specification

Claims 14 & 16 are objected to because of the following informalities: The term multipartate is not clearly defined nor is found in a dictionary, the examiner requests the applicant clearly state the meaning of this term, for examination it is assumed that a multipartate port is one with a "fillet" within it therefore splitting the port. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 & 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Uber, III et al (US Patent No. 6397098B1). Uber, III et al discloses an injector arrangement comprising a remote control 150 generating a variable signal for fluid discharge rate seen in figure 2, a computer 92 coupled to the remote control regulating a motor control

voltage, a syringe 40, and a motor in injection control unit 120 coupled to the computer and the syringe, the motor causing fluid to discharge from the syringe at a desired rate.

With regards to claim 2, the syringe as seen in figure 1 which includes a cylinder, an inlet port for connection to a supply of fluid which is the end by the piston rod in which fluid can be entered when the rod is removed, an outlet port seen as the end of 40 closer to 50 for connection to a patient, and a plunger movable in said cylinder and driven by the motor.

With regards to claim 3, the remote control 150 includes a handheld device having an actuator for generating a signal seen in figure 2 connected to 120.

With regards to claim 5, wherein the computer receives an ECG signal derived from a patient and coordinates operation of said syringe with the ECG signal, see col. 10 lines 25-31.

Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Reilly et al (US Patent No. 5795333). The Reilly et al reference discloses an injector kit seen in figures 1 & 6 for an angiographic injector system comprising a syringe 22 comprising a syringe body having a distal end and a proximal end, the syringe body defining a pumping chamber and an inlet port seen as the open end of the syringe in which the plunger is placed; a syringe end wall located at the distal end of said syringe body having a flat face for the mating engagement with the syringe holder, said end wall defining an outlet port 86; and a syringe plunger 38 located in said pumping chamber

adapted for reciprocal motion between a position proximate to said proximal end and said distal end.

Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg et al (Us Patent No. 4596575) or Rubinstein (US Patent No. 3888239). Rosenberg et al and Rubinstein both disclose injection devices which automatically refill a syringe, the method comprising sensing a volume of fluid in a chamber of the syringe, comparing said volume in said chamber with a preset amount of fluid necessary for a subsequent injection, retracting a plunger within said chamber of said syringe to a predetermined limit if the preset amount of fluid necessary for a subsequent injection is less than the volume of fluid sensed in said chamber, wherein predetermined limit maximally fills said chamber of said syringe, wherein the predetermined limit is less than a maximal volume of said chamber, with respect to Rosenberg see col. 1 line 60 – col. 2 line 5, col. 2 line 66 – col. 3 line 7, col. 5 line 65 – col. 6 line 17 and with regards to Rubinstein see col. 2 line 57 – col. 3 line 7 and col. 6 line 5 – 59.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uber, III et al (US Patent No. 6397098B1) in view of Ginngo et al (US Patent No. 5868728). Even though Uber, III et al does not disclose a foot operated device remote control attention is directed to Ginngo et al. The Ginngo reference teaches the use of a foot operated remote control to control a signal for syringe contents expulsion in col. 3 lines 15-28. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the foot operated remote control of Ginngo in the Uber, III reference in order to provide the user with the flexibility of utilizing both hands since they would be not be occupied by a handheld remote.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uber, III et al (US Patent No. 6397098B1) in view of Karg (US Patent No. 5267964). Even though Uber does not disclose a low pressure system and a manifold including a shell, first port, second port, third port attention is directed to Karg. The Karg reference discloses a low pressure system (12,28) and a manifold including a manifold shell, a first port 22, a second port 50, and a third port 20, the manifold including a valve 37 wherein the manifold has a first state being when the second and third port are connected while the first and third ports are always disconnected as seen in figure 2 and a second state being when the first and second ports are disconnected and the first and third ports are always disconnected as seen in figure 3.

With regards to claim 8, the valve is normally biased to the first state due to the constant pressure provided by the low pressure system on the valve 37 and is switchable to the second state when fluid pressure from said syringe reaches a predetermined pressure level as seen in figure 3.

Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the low pressure system and manifold of Karg into the device of Uber in order to provide a syringe refilling means as well as a backflow prevention means.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uber, III et al (US Patent No. 6397098B1) in view of Karg (US Patent No. 5267964) in further view of Melsky et al (US Patent No. 5575770) or Weissman et al (US Patent No. 5556001) or Clair et al (US Patent No. 4471775). Even though Uber in view of Karg does not disclose the use of a spring-biased spool valve attention is directed to Melsky or Weissman or Clair. The Melsky, Weissman, and Clair references all teach the use of a spring-biased spool valve for separating different ports for uses in separate instance. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to use a spring-biased spool valve in the invention of Uber in view of Karg in order to provide a rigid and consistent valving system.

Claims 6 & 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uber, III et al (US Patent No. 6397098B1) in view of Karg (US Patent No. 5267964).

Even though Uber does not disclose a low pressure system and a three port manifold and the manifold having a passively bias able valve including a first state and a second state attention is directed to Karg. The Karg reference when shown in view of claims 6 & 11 discloses a low pressure system (12,28) and a manifold 10 including a manifold shell, a first port 22, a second port 50, and a third port 20, the manifold including a valve 37 having a first state seen in figure 1 and a second state seen in figure 2 in which the valve is constructed and arranged to be passively biased to said first state. Therefore, it would be obvious to one of ordinary skill in the art to incorporate the low pressure system and manifold of Karg into the device of Uber in order to provide a syringe refilling means as well as a backflow prevention means.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uber, III et al (US Patent No. 6397098B1) in view of Karg (US Patent No. 5267964) in further view of Sinnett et al (US Patent No. 4670006). Even though Uber in view of Karg does not disclose a low pressure system including a pressure transducer and a pump attention is directed to Sinnett et al. The Sinnett et al reference teaches the use of a pressure transducers and a pump in fluid communication with a pressure system in figure 5, also see abstract and col. 5 line 15-25 and col. 6 line 57 – col. 7 line 36. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the pressure transducer and pump of Sinnett into the device of Uber in view of Karg in order to better control the pump output.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al (US Patent No. 5795333) in view of Karg (US Patent No. 5267964). Even though Reilly et al does not disclose a manifold attention is directed to Karg. The Karg reference discloses a manifold 10 including a manifold shell, a first port 22 in fluid communication with said syringe, a second port 50 in fluid communication with a patient, and a third port 20 connectable to a low pressure system. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the manifold of Karg into the device of Reilly in order to provide the injector the ability to add a low pressure system such as that of Karg in order to provide a refilling means.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al (US Patent No. 5795333) in view of Karg (US Patent No. 5267964) in further view of Averette (US Patent No. 5012845). Even though Karg discloses a patient tube and a low pressure tube, it does not disclose a flush tube therefore attention is directed to Averette. The Averette reference teaches a fluid injector utilizing a flush tube in col. 10 lines 50-59. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the flush tube of Averette into the device of Reilly in view of Karg in order to provide a way to flush contaminants out of the system.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al (US Patent No. 5795333) in view of Karg (US Patent No. 5267964) in further view of

Averette (US Patent No. 5012845) in further view of Harrison et al (US Patent No. 5554119). Even though Reilly in view of Karg in further view of Averette does not disclose the use of a patient catheter attention is directed to Harrison et al. Harrison et al discloses the use of a drug delivery patient catheter. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the catheter of Harrison into the device of Reilly in view of Karg in further view of Averette in order to provide a means to open a passageway and to keep it open for the contrast media.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al (Us Patent No. 4596575) or Rubinstein (US Patent No. 3888239) in view of Reinicke (US Patent No. 4684365). Even though Rosenberg or Rubinstein do not explicitly state the step of purging air from the chamber of the syringe attention is directed to Reinicke. The Reinicke reference teaches the step of purging air from the chamber of the syringe col. 7 line 47-51. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the air purging step of Reinicke into the method of Rosenberg or Rubinstein in order to provide a safer device and to allow for a faster refill.

Claims 12-13 & 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uber, III et al (US Patent No. 6397098B1) in view of Karg (US Patent No. 5267964) in further view of Manska (US Patent No. 4919167). Even though Uber does not disclose a low pressure system, a manifold with three ports, a manifold wiper with

ridges, a manifold shell with a cone and a ring attention is directed to Karg in view of Manska. With regards to claims 12-13, Karg discloses a low pressure system and a manifold with 3 ports while Manska discloses a manifold wiper seen in figures 1 & 4 as the front of 140 including at least two ridges seen as 54 contacting the ends of 27, one ridge comprising the top and one ridge comprising the bottom side and including at least one protrusion seen as the face of 27 contacting the wiper at both ridges seen in figure 1. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the low pressure system and manifold and manifold wiper of Manska and Karg into the device of Uber in order to provide a means to refill the syringe and a check valve means to reliably control the flow of the fluids.

With regards to claim 17-18, Manska discloses a manifold shell including an inner surface having a cone shape at one end of said manifold shell further including a wedge shaped annular ring as seen in figure 4 on the left side. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the cone shape and ring manifold of Manska into the device of Uber in view of Karg in order to provide the port with a more focused means of delivery.

Claims 14 & 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uber, III et al (US Patent No. 6397098B1) in view of Karg (US Patent No. 5267964) in further view of Armour (US Patent No. 3940224). Even though Uber in view of Karg does not disclose a multipartate opening port attention is directed to Armour. The Armour reference discloses a multipartate port means through the use of a fillet such as

that seen in figures 3 & 4. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the multipartate opening port of Armour into the device of Uber in view of Karg in order to provide a means of allowing fluid flow while not constraining expansion of a wiper.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uber, III et al (US Patent No. 6397098B1) in view of Karg (US Patent No. 5267964) in further view of Simmons (US Patent No. 3746038). Even though Uber in view of Karg does not disclose an oscillation reduction port attention is directed to Simmons. The Simmons reference discloses an oscillation reduction means that can be placed in the port, see col. 3 lines 29-35. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the oscillation means of Simmons into the device of Uber in view of Karg in order to eliminate oscillations through the port.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Scheller (US Patent No. 4837857) also discloses the use of a foot operated device for a remote control. Brown et al (US Patent No. 4604093) also teaches the purging air step for refilling a syringe.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BHH

BHH

MJ Hayes

MICHAEL J. HAYES
PRIMARY EXAMINER